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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,654 10/25/99 AMMERMANN E 47968

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HM12/1207

EXAMINER

KRUSE, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.

09/403,654

Applicant(s)

AMMERMANN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-48 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant election with traverse of Group I, Claims 29-46 in Paper #5, filed 6 November 2000 is acknowledged. The traversal is on the ground(s) that Claim 48 is drawn to the product of the process of Claim 45, and thus the claims are inextricably linked by a special technical feature under PCT Rule 13.2. This is not found persuasive because Group I (Claims 29-46) is broadly drawn to an expression cassette comprising a wide genus of genes that encode fungicide-binding polypeptides. Therefore, there is no single special technical feature under PCT Rule 13.2 that links the expression cassette of Group I (Claims 29-46) and the fungicide-binding antibody of Group III (Claim 48).

The requirement is still deemed proper and is therefore made FINAL.

2. This application contains claims 47 and 48 drawn to an invention nonelected with traverse in Paper No. #5, filed 6 November 2000. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statement filed 25 October 1999 has been considered, but the references listed under Other Documents do not comply with 37 CFR 1.98 and will not be published on the face of the issued patent. If Applicant wishes the afore mentioned documents to be published on the face of the issued patent a supplemental IDS furnishing the full citations should be timely submitted in response to this Office Action that is in compliance with 37 CFR 1.98.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

6. The abstract of the disclosure is objected to because it is not descriptive of the claimed invention. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities: At page 9, line 46 "trebled" should read -- tripled -- . Appropriate correction is required.

8. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

9. The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

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- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

10. Claim 42 is objected to because of the following informalities: The terms "agrobacterium" should read -- Agrobacterium -- or -- *Agrobacterium* -- and "Agrobacterium tumefaciens" should read -- Agrobacterium tumefaciens -- or -- *Agrobacterium tumefaciens* --. Appropriate correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 37-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

13. Claims 37-40 and 45 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

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1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). In addition, Claim 45 appears to be directed to a method, "production" is not a category of patentable subject matter.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 29-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a process for producing a BAS 490F-tolerant transgenic plant by transforming said plant with a nucleotide sequence that encodes a BAS 490F-binding polypeptide, an expression cassette comprising said nucleotide sequence and a transgenic plant comprising said nucleotide sequence.

Applicant describes a process for producing a BAS 490F-tolerant transgenic plant by transforming said plant with a nucleotide sequence that encodes a BAS 490F-binding single-chain antibody fragment (scFv), an expression vector comprising said nucleotide sequence and a transgenic plant.

Applicant does not describe the nucleotide sequence encoding the scFv nor has Applicant deposited ~~of~~ the disclosed scFv nucleotide sequence. In addition, Applicant

has not described the isolation of any other BAS 490F-binding polypeptide encoding nucleotide sequence that would be required to practice the claimed invention.

Hence, it is not clear from the instant specification that Applicant was in possession of the invention as broadly claimed.

Claims 29-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a process for producing a BAS 490F-tolerant transgenic plant by transforming said plant with a nucleotide sequence that encodes a BAS 490F-binding polypeptide, an expression cassette comprising said nucleotide sequence and a transgenic plant comprising said nucleotide sequence.

Applicant teaches a process for producing a BAS 490F-tolerant transgenic plant by transforming said plant with a nucleotide sequence that encodes a BAS 490F-binding single-chain antibody fragment (scFv), an expression vector comprising said nucleotide sequence and a transgenic plant.

Applicant does not teach the nucleotide sequence encoding the scFv nor has Applicant deposited ~~of~~ the disclosed scFv nucleotide sequence. In addition, Applicant ~~has~~ does not teach the isolation of any other BAS 490F-binding polypeptide encoding nucleotide sequence that would be required to practice the claimed invention.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be

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necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for DNA isolation requires guidance as to what sequences are critical for probe and PCR nucleotide sequence recovery methods, PCR reaction conditions and hybridization conditions. Applicant does not provide guidance for isolation of all nucleotide sequences encoding a polypeptide that binds BAS 490F nor does Applicant provide guidance for isolating the genus of nucleotide sequences, which encode peptides that bind BAS 490F, *e.g.*, the fungicide's target cytochrome c oxidoreductase, mutations thereof or fragments thereof. In addition, Applicant does not teach any other method of identifying and isolating BAS 490F-binding polypeptides and the nucleotide sequences that encode said polypeptides, other than that for the antibody scFv-antiBAS 490F, whose nucleotide sequence has not been taught.

When the *Wands* factors are weighed, it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not enabled.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

17. Claims 29-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 29 line 3 and Claim 45 line 2, the term "expressing" is not a process step since it is the plant which expresses. It is suggested that the phrase -- transforming a plant with an exogenous gene encoding -- be used, and deleting "in the plant" at line 4 of Claim 29.

At Claims 29-32, 37 and 38, the term "exogenous" is indefinite. It is suggested that the phrase -- isolated nucleotide sequence encoding a -- be used.

At Claim 31 line 3, the term "derived" is indefinite and does not state that the claimed "fragment" is actually from a "complete antibody".

At Claim 32 line 1, the phrase "composed of" should read -- comprising -- .

At Claim 32 line 2, the phrase "expression of" is improper and should be deleted.

Claim 33 recites the limitation "constitutive promoter" in line 2. There is insufficient antecedent basis for this limitation in the claim.

At Claim 34 line 2, the phrase "to be expressed is the gene of" is indefinite, the term -- encodes -- is suggested.

Claim 35 recites the limitation "or gene fragment" in line 2. There is insufficient antecedent basis for this limitation in the claim.

At Claim 35 line 4, the phrase "a translation fusion with other functional proteins" is confusing. It is suggested that the phrase -- a gene encoding a fusion protein -- be used.

At Claim 35 line 5, the word "and" suggests that all of the genes encoding the listed polypeptides must be "expressed". It is suggested that -- or -- be used or proper Markush wording be used.

Claim 35 is improperly dependant, Claim 32 does not recite the limitation "gene or gene fragment of the ... polypeptide". It is suggested that the claim be reworded to recite -- further comprises a gene encoding another functional protein selected from the group consisting of ... which is translationally fused to the gene encoding the exogenous methyl ... -- .

At Claim 35 line 6, the word "employed" is indefinite, as it does not state the metes and bounds of the claimed invention.

Regarding Claims 35 and 36, the phrase "for example" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

At Claim 36 line 2, the phrase "polypeptide gene to be expressed" is indefinite and lacks antecedent basis, the phrase should read -- wherein the gene encoding an exogenous ... -binding polypeptide -- .

At Claim 36 line 2, the word "obtained" is indefinite, the term -- isolated -- is suggested.

Claims 37-40 provide for the use of the expression cassette as claimed in Claim 32, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite

where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

At Claim 37 line 3 and Claim 38 line 4, the word "which" is unclear. The claims should be amended to recite the phrase -- wherein the plant ... expresses the-- .

At Claim 41 lines 4-5, the phrase "an entire plant and protoplasts of plant cells." is indefinite as it does not state where the gene sequence is going and insinuates that all of the listed plant tissues must be present for the process. It is suggested that the phrase -- , into an entire plant, protoplasts, callus tissue or plant cells." -- be used. However, preamble of the claim recites transformation of a plant. Introducing into plant cells, callus or protoplasts is an insufficient method step for such a method, *i.e.* require regeneration of a transgenic plant from transformed cells.

At Claims 42, 43 and 44, the phrase "effected with the aid of" is indefinite. It is suggested that the phrase -- performed by -- be used. In addition, Applicant should further limit "introducing" and not "transformation" because "introducing" is the actual method step.

At Claim 45 line 3, the phrase "such a polypeptide" is indefinite, it is suggested that the phrase -- said polypeptide -- be used.

At Claim 46 line 1, the phrase "an expression cassette" is indefinite and should read -- the expression cassette -- .

The term "tolerance" in claim 46 is a relative term, which renders the claim indefinite. The term "tolerance" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

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art would not be reasonably apprised of the scope of the invention. Applicant must state the basis by which the term "tolerance" is defined in the claim. Also, it is unclear to what the expression cassette imparts tolerance, the plant or BAS 490F?

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Paula Hutzell can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1234.

A handwritten signature in cursive script, reading "Amy Nelson".

AMY J. NELSON, PH.D
PRIMARY EXAMINER

David H. Kruse, Ph.D.
5 December 2000